

Respiratory Protection for Healthcare Personnel: Understanding Fit and Filtration and Why Compliance Matters

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***Webinar, University of Iowa Heartland Center for Occupational
Health & Safety - January 7, 2014***

Learning Objectives

Upon completion of this presentation participants will:

- **Have a better appreciation for when respirators should be used in healthcare settings**
- **Have a better understanding of the scientific basis for how and why respirators work**
- **Be able to identify the roles that fit, filtration, and compliance contribute to protection**
- **Be aware of NIOSH research that seeks to encourage development of a “next generation” respirator for healthcare personnel (HCP)**

NIOSH PPT / NPPTL

Vision & Mission

The **VISION** is to be the leading provider of quality, relevant, and timely PPT research, training, and evaluation.

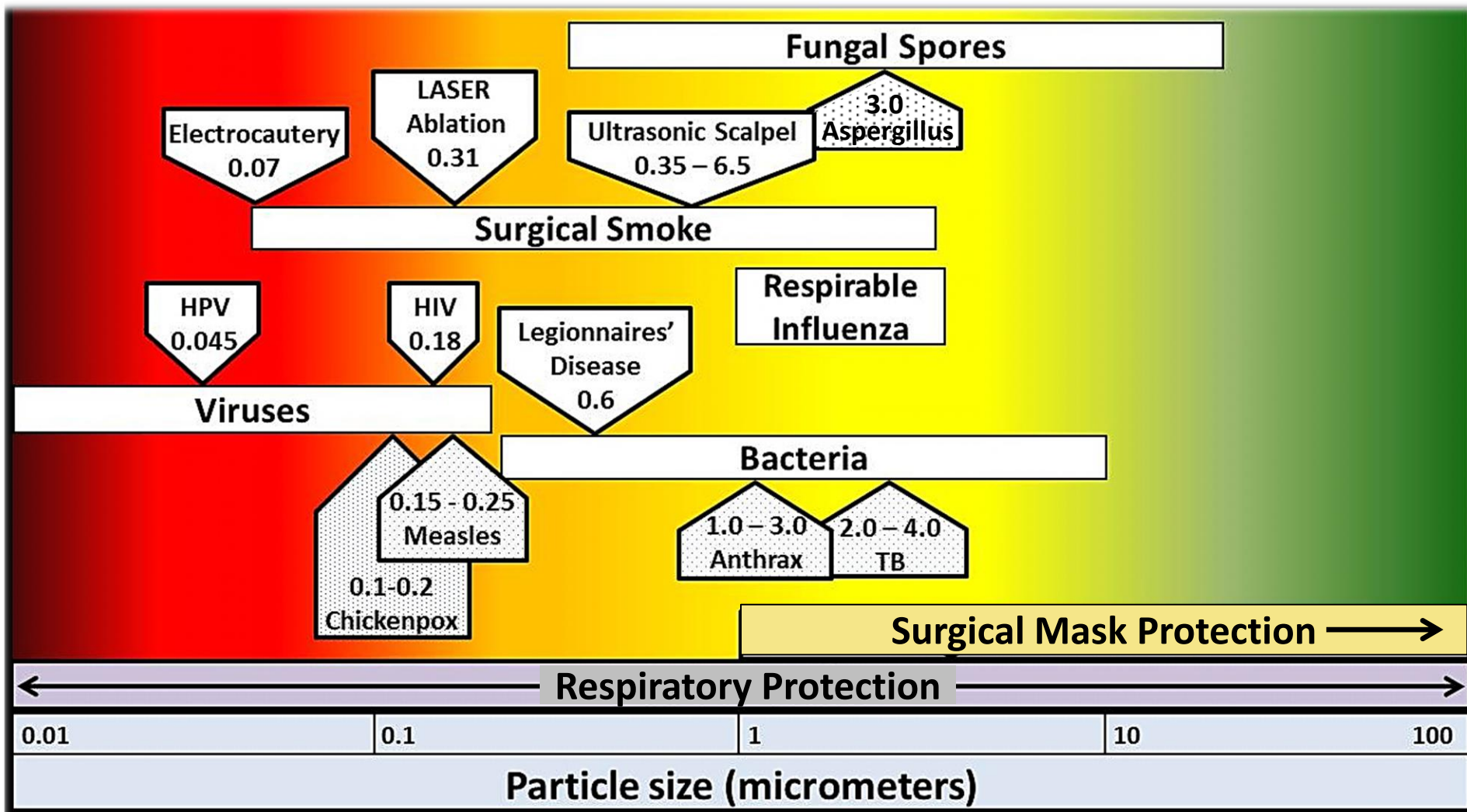
The **MISSION** of the PPT program is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies (PPT).



Why HCP Respiratory Protection is a Priority

- **Healthcare is the fastest-growing sector of the U.S. economy, employing over 18 million workers**
- **HCP are at higher risk of exposure to infectious respiratory pathogens than workers in non-healthcare settings**
- **Preferred methods of reducing exposure (elimination, substitution, administrative, and engineering controls) are often not possible or practical to implement, especially during an emerging outbreak or pandemic**

Selected Inhalation Hazards



When should a respirator be worn?

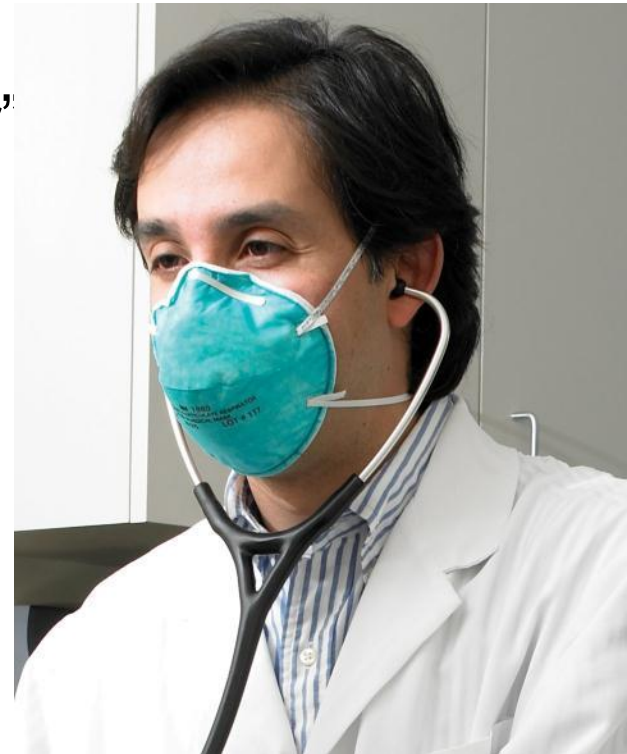
- Respirators are often recommended to be used when in close contact with patients suspected of having an aerosol transmitted disease. Some *possible examples include:
 - Influenza (Avian strains capable of causing serious disease in humans or during certain medical procedures)
 - Varicella disease (chickenpox, disseminated shingles)
 - Measles
 - Monkeypox
 - Severe acute respiratory syndrome (SARS)
 - Smallpox
 - Tuberculosis (TB)
 - *Note: Infection control guidance for specific pathogens can vary by jurisdiction and for different medical procedures

Infection Control Perspective

Type	Facial/Respiratory Personal Protective Equipment (PPE)
Standard	Surgical mask and goggles, or faceshield should be worn during activities likely to generate splashes or sprays of blood or body fluids
Contact	Same as standard
Droplet	Surgical mask upon entering the room
Airborne	Respiratory protection upon entering the room

Respiratory Protection in Healthcare

- **N95 Filtering Facepiece Respirators (FFRs)** are the most commonly used type of respirator in healthcare
 - NIOSH 42 CFR Part 84
 - FDA “Surgical N95 respirator”



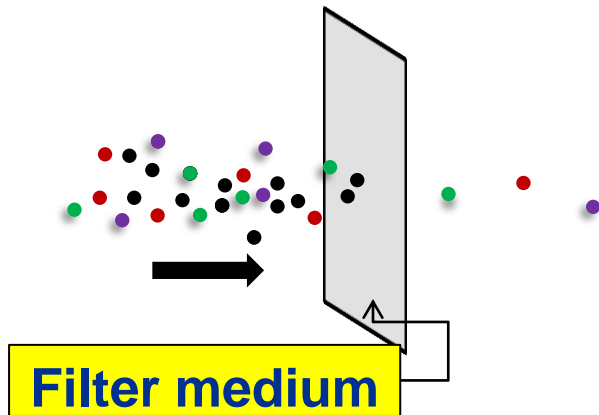
FFR Basics

- Entire facepiece is composed of the filtering medium
- Designed to form tight face seal
- Approximate cost: <~\$2 each
- Disposable

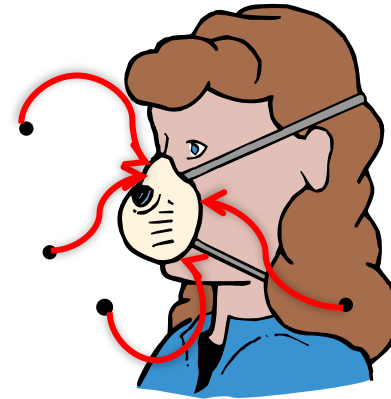


How Particles Get Past Masks

Filter penetration



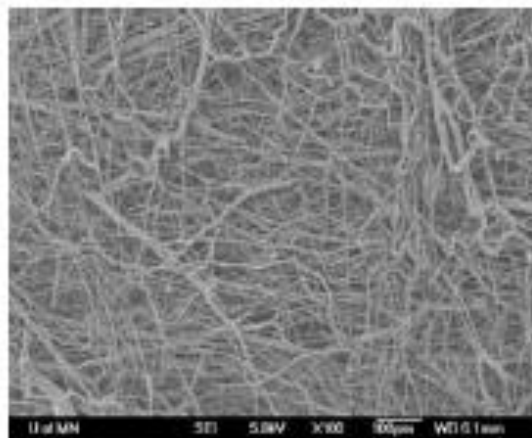
Face seal leakage



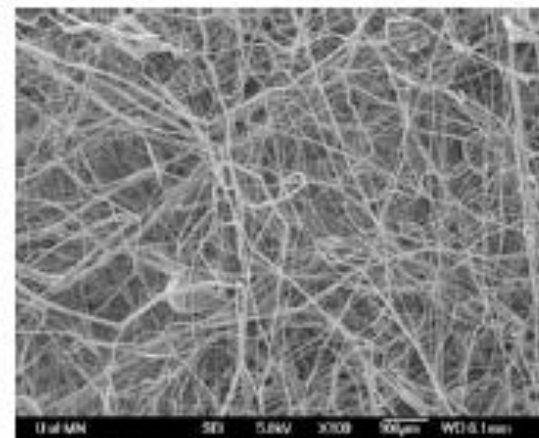
What does a Filter Look Like?

How Does it Work?

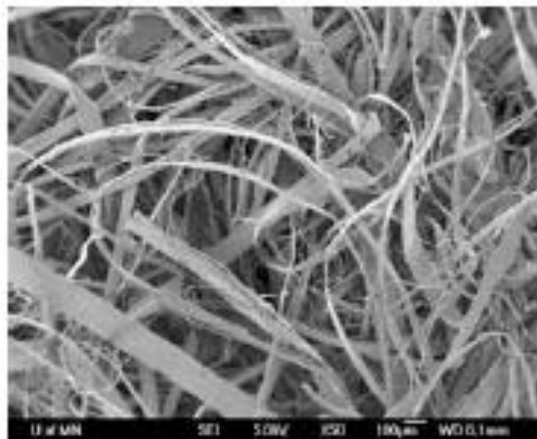
- FFR filters are typically made from sheets of nonwoven polymer microfibers
- Gaps between the fibers allow air to move through them easily
- Particles in the air are trapped when they collide with one of the fibers



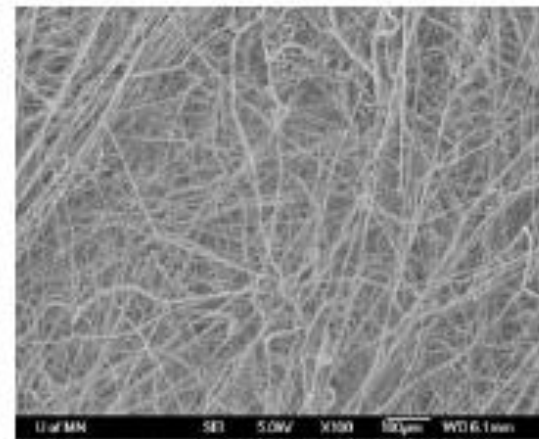
(a) Media A ($\times 100$)



(b) Media B ($\times 100$)

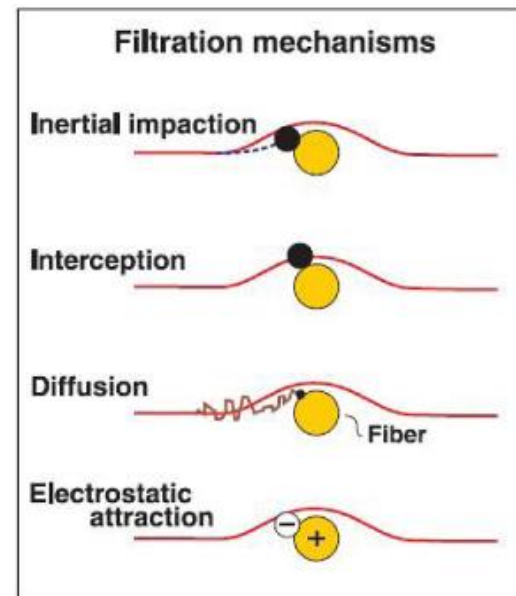
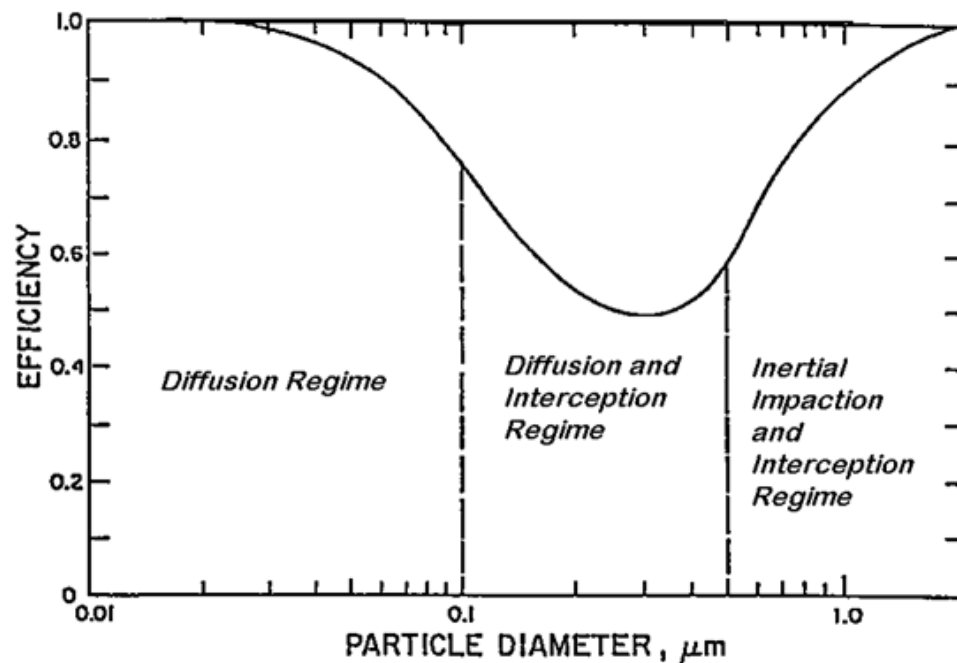


(c) Media C ($\times 50$)



(d) Media D ($\times 100$)

Science of Filtration is Established



- Filtration theory says...
 - Size of the particle is important!
 - Type of particle (infectious or inert) is not important!

Summary: Filter Efficiency for Facial and Respiratory PPE

Respirator/Mask Type	Filter Efficiency* (%)
NIOSH N95 FFR	98.76 – 99.39
NIOSH P100 FFR	99.978 - 99.997
FDA Surgical Mask	11.94 – 98.42
Unregulated Dust Mask	12.98 - 99.00

Sample sizes: N95 FFR = 5; P100 FFR = 2, Surgical mask = 5, Dust mask = 5;

* Polydisperse Aerosol with Mass Median Diameter ~240 nm (TSI 8130, 85 L/min)

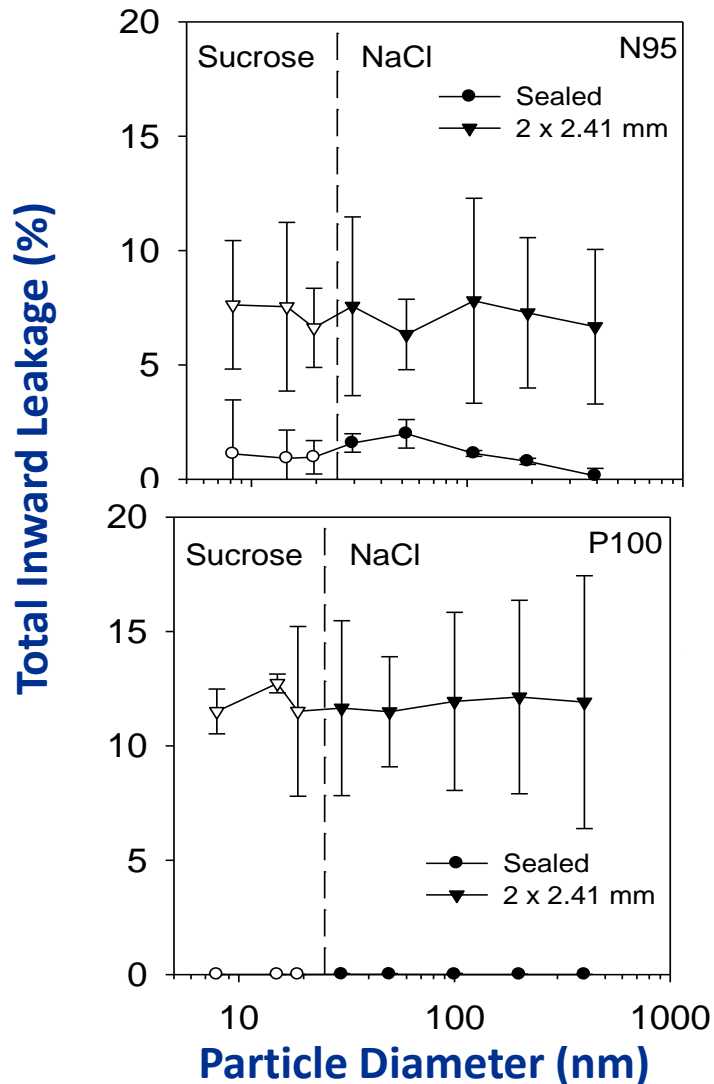
Average Filter Efficiency

N95 FFR model	0.1 µm inert bead	0.1 µm H1N1 influenza	0.8 µm inert bead	0.8 µm H1N1 influenza
A	99.42%	99.26%	99.85%	99.27%
B	99.88%	99.52%	99.90%	99.13%
C	99.17%	99.43%	99.72%	99.93%
D*	>99.99%	>99.99%	>99.99%	>99.99%
E*	99.64%	99.84%	99.94%	99.23%

Key finding: equivalent filter efficiency for inert bead and viable H1N1 influenza aerosols.... “a particle is a particle”

* N95 FFR with antimicrobial coating; all tests done at 85 l/min flow rate

Faceseal Leakage vs. Filter Penetration



- Leak size was the largest factor affecting the number of particles inside the FFR in manikin tests
- Minimizing face seal leakage is necessary for your protection

Proper Donning Practices are Important for Minimizing Face Seal Leakage

- In general, higher fit factors (i.e., less face seal leakage) and less variation were found when performing a user seal check compared with not performing one
- User seal check is not a substitute for a fit test, but offers some benefits for users in a respiratory protection program (e.g., fewer poor donnings)

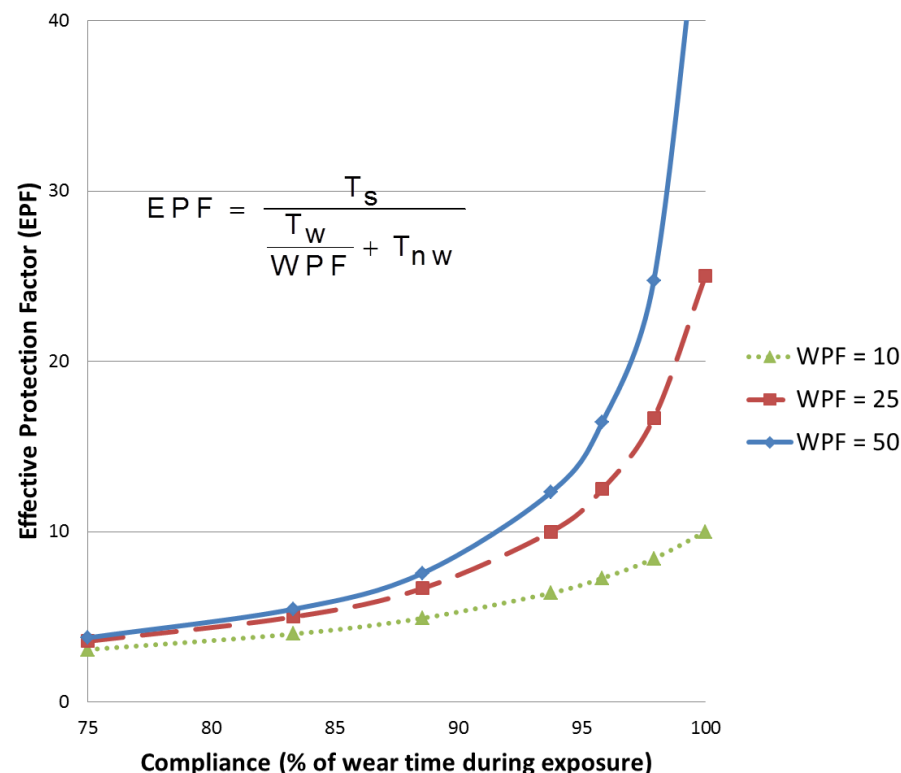


Workplace Studies

- **FFRs can reliably reduce particle exposures >10-fold when used in the context of a complete respirator program**
 - Includes studies of non-infectious bioaerosols
- **No clinical/field studies in healthcare have met criteria for a workplace protection factor study**
 - Challenges: lack of exposure limits/infectious dose, exposures outside of work, multiple interventions, compliance, detection limits
- **Respiratory Protection Effectiveness Clinical Trial (ResPECT)**

Compliance is Critical

- If a respirator is not worn properly or at all during the exposure, it will provide little protection (if any)
- Compliance needs to be > ~75% to see a significant difference in EPF (i.e., exposure reduction) for better performing respirators



T_e = Exposure duration, T_w = Time Worn, T_{nw} = Time Not Worn, WPF = Workplace Protection Factor

Issues & Solutions

Reported Reasons for PPE Non-Compliance

Lack of accountability for non-compliance

Workload issues

Time constraints

Risk perception

Effectiveness concerns

Availability

Uncomfortable

Interference with work tasks

Inability to communicate

Some Reported Ways to Improve Compliance of PPE and Other Interventions

Improve safety culture

Better training strategies

Develop & communicate clear recommendations

Risk communication

Conduct effectiveness studies

More accessible / less burdensome interventions

Better PPE

Project BREATHE - Better Respiratory Equipment using Advanced Technology for Healthcare Employees

- **Objective:** To improve HCP respirator compliance
- **Approach:** Encourage the development of advanced technologies for the next generation of HCP respirators that are more comfortable and tolerable
- **Partnership:** Veterans Health Administration (VHA)

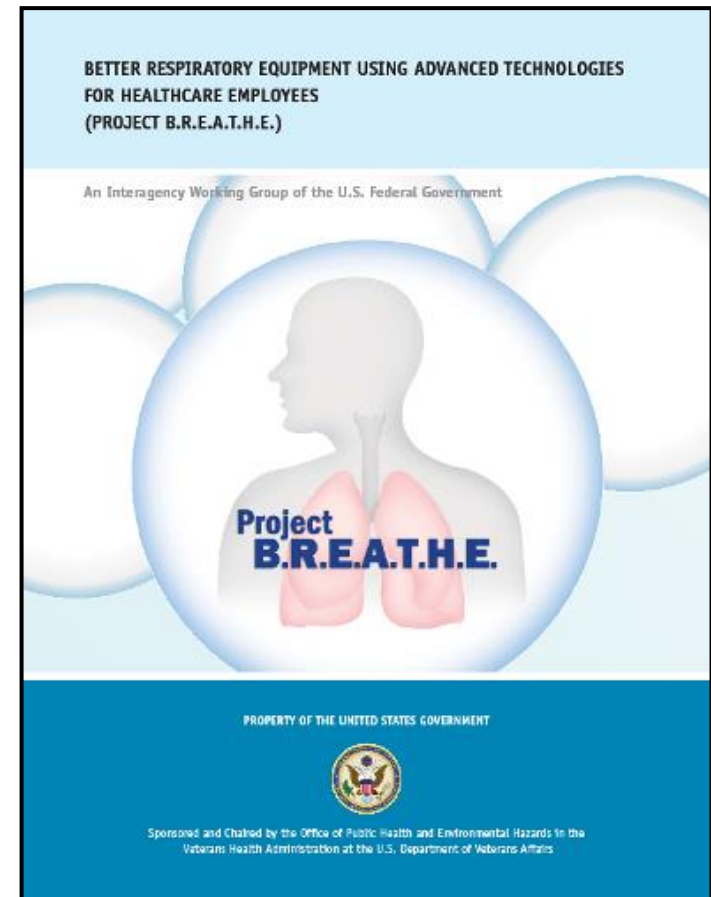


Project BREATHE Working Group


- **Respirators should:**

- Perform their intended functions safely and effectively (9 requirements identified including fit & reusability/fomite concerns)
- Support, not interfere with, occupational activities (5 requirements... speech, hearing, etc.)
- Be comfortable and tolerable for the duration of wear (10 requirements... breathing resistance, facial pressure, etc.)
- Comply with current standards and guidelines (4 requirements... OSHA, NIOSH, FDA)

- **Need a “B95” respirator for HCP**

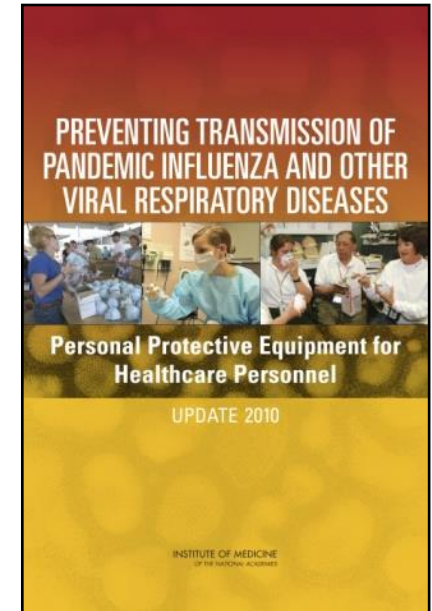


Path Forward

Develop clinically-validated “B95” test methods	“B95” prototype development	Development of a “B95” standard
<ul style="list-style-type: none"> • Comfort • Fit • Occupational interference 	<ul style="list-style-type: none"> • Collaborations with academia and industry 	<ul style="list-style-type: none"> • Draft “B95” requirements, criteria, and test methods developed • Focus on comfort & fit

Summary & Next Steps

- **Agree with 2011 IOM report**
 - Important advances have been made in some areas (filtration, physiological impact) since 2008, but other areas need to be fully addressed (e.g., fit, integration, effectiveness of controls on disease transmission, etc.)
- **Next steps (2014-)**
 - Continuing on-going efforts related to fit (inward leakage) and towards a B95 consensus standard
 - Publishing an updated research roadmap (“action plan”)
 - Expanding program area in improving compliance with respirator selection and use practices



Acknowledgements

- Heartland Center for Occupational Health & Safety
- AFRL: Del Harnish, Brian Heimbuch, and Joe Wander
- NPPTL/TRB Surveillance, Communications, & Scientific Support Team: Debbie Novak, Jackie Krah, and Lindsay Stradtman
- NPPTL/TRB Respiratory Protection Team: Ziqing Zhuang, Mike Bergman, Ed Fisher, Samy Rengasamy, and Andy Palmiero
- NPPTL/TRB Human Performance Team: Ray Roberge, Jon Williams, Kenny Kim, Jeff Powell, and Eddie Sinkule
- AIHA RPC working group: Larry Janssen (chair)
- VHA's Center for Occupational Health and Infection Control (COHIC): Lew Radonovich, Megan Gosch, and Aaron Eagan

Quality Partnerships Enhance Worker Safety & Health



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Disclaimer:

The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

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- **Slide 5. Adapted from:**

- Benson et al. [2013]. Proper use of surgical N95 filtering facepiece respirators and surgical masks in the OR: Surgical smoke plume and how to best protect yourself. *AORN J.* 97(4): 458-467

- **Slide 6. Example lists of aerosol transmitted diseases**

- <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>
- <https://www.dir.ca.gov/title8/5199a.html>
- <http://www.cdc.gov/niosh/topics/ryanwhite/>

- **Slide 7. Table adapted from:**

- Healthcare Infection Control Practices Advisory Committee (HICPAC), 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings.
- Goldfrank, L.R., and C.T. Liverman: Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers: National Academies Press, 2008.

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- Slide 8. Photos courtesy of 3M
- Slide 9. Photos courtesy of Ray Roberge (NPPTL) and 3M
- Slide 11. Reference
 - <http://www.cdc.gov/niosh/npptl/researchprojects/pdfs/NanoparticleFinalReport041006.pdf>

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- Rengasamy et al. [2011] Total inward leakage of nanoparticles through filtering facepiece respirators. *Annals of Occupational Hygiene*; 55: 253–63.
- Photo courtesy of Samy Rengasamy (NPPTL)

- **Slide 16. Reference**

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- **Slide 18. Figure adapted from**

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- Janssen et al., [2013] The Use of Respirators to Reduce Inhalation of Airborne Biological Agents, Journal of Occupational and Environmental Hygiene 10: D97–D103.

- **Slide 19. For additional information:**

- http://www.cdc.gov/niosh/docket/review/docket129A/pdfs/HCWRoadmapFrameDocV3_6-7-13.pdf

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- **Slide 21. References**

- <http://www.publichealth.va.gov/docs/cohic/project-breathe-report-2009.pdf>
- Gosch et al., [2013] B95: A new respirator for health care personnel, American Journal of Infection Control 41(12):1224-30.

- **Slide 22. For additional information:**

- <http://www.cdc.gov/niosh/npptl/resources/certpgmspt/meetings/06182013/HealthcareInvitationLtr06182013.html>

- **Slide 23. Link to download the IOM report**

- http://www.nap.edu/catalog.php?record_id=13027